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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,124	10/17/2001	Allan Green	26-98A	9503

7590 07/31/2006  
John P. White, ESQ  
COOPER & DUNHAM LLP  
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NEW YORK, NY 10036

EXAMINER
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MCELWAIN, ELIZABETH F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/981,124	GREEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Elizabeth F. McElwain	1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 May 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26-29 and 31-49 is/are pending in the application.
- 4a) Of the above claim(s) 44-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-29 and 31-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/059,769.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

The amendment filed May 5, 2006 and the arguments filed January 9, 2006 have been entered.

Claims 26, 31 and 42 are currently amended claims that are part of the elected invention.

Claims 26-29, 31-49 are pending.

Claims 26-29 and 31-43 are examined on the merits.

### *Election/Restrictions*

Applicants' arguments that claims 44-49 were improperly restricted is not found persuasive because a product may be restricted from the process of using, as stated previously.

The requirement is still deemed proper and is therefore made FINAL.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction

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requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims 44-49 drawn to an invention nonelected with traverse, and claim 26, which recites SEQ ID numbers 2, 6, 8 and 20 that are non-elected. In addition, claim 26 now recites additional SEQ ID numbers 21-24, which would have been restricted had they been presented in the original claims. A complete reply to the final rejection must include cancellation of nonelected claims and non-elected subject matter or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Claim Objections***

Claim 26 and all claims dependent thereon, are objected to for reciting non-elected SEQ ID numbers. Applicants elected SEQ ID NO: 3 and 4 in the response filed May 5, 2005.

Deletion of the non-elected subject matter is required.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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2. Claims 26-29 and 31-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26, and claims 27-29 and 31-43 dependent thereon, are indefinite and confusing with regard to the three histidine-rich regions for which each is identified by two SEQ ID numbers, and the histidine-rich regions of (ii) and (iii) seem to be duplicated. It is unclear if each of (i), (ii) and (iii) are one or both of the SEQ ID numbers set forth; and it is unclear how the two SEQ ID numbers relate to designated histidine rich sequences that may have 3 or 4 histidines or 2 or three histidines.

1. Claims 26-29 and 31-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transgenic Arabidopsis and flax plants that are transformed with a nucleic acid of SEQ ID NO: 1 or a nucleic acid encoding the delta-12 epoxygenase of SEQ ID NO: 2, does not reasonably provide enablement for any transgenic plant species transformed with a nucleic acid encoding any enzyme having any epoxygenase activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons set forth in the last office action.

2. Applicants' arguments filed January 9, 2006 have been fully considered but they are not persuasive. Applicants urge that Example 13 predicts epoxygenase activity of SEQ ID NO: 6

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and 20. However, the Examiner maintains that there is no clear showing that it is a delta-12 epoxygenase coding sequence, such as the production of vernolic acid.

Applicants argue that they have provided a means of testing that would not require undue experimentation and no definitive evidence is required. In addition, applicants assert that the '270 patent application of Hildebrand et al and U.S. Patent of Hitz et al provide evidence that applicants' disclosure is enabling. However, the Examiner maintains that applicants have stated that Hildebrand et al required the teachings of both applicants and of Hitz et al to clone epoxygenase sequences. Applicants disclosure on its own was not sufficient for enablement. Furthermore, the Examiner maintains that undue experimentation would be required to identify and test each of the sequences encompassed by the claims to determine whether they coded for delta-12 desaturase activity and would result in the production of vernolic acid in a transformed Arabidopsis plant.

### ***Conclusion***

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Elizabeth F. McElwain, Ph.D.  
Primary Examiner  
Art Unit 1638

EFM